Docket No.: F-8181

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Before the Board of Patent Appeals and Interferences

Applic. No.	:	10/802,354	Confirmation No.: 3618
Inventor	:	Laurence M. Shanley	
Filed	:	March 16, 2004	
Title	:	Needle Cap Assembly for Syringe	
TC/A.U.	:	3763	
Examiner	:	Laura A. Bouchelle	
Customer No.	:	24131	

AMENDED

BRIEF ON APPEAL

This is an appeal from the final rejection in the Office action dated December 20, 2006, finally rejecting claims 1-15.

Payment in the amount of $250.00 to cover the fee for filing the *Brief on Appeal* was submitted on May 22, 2007.

Real Party in Interest:

This application is currently not assigned. The inventor, Laurence M. Shanley, is the real party in interest.

Related Appeals and Interferences:

No related appeals or interference proceedings are currently pending which would directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

Status of Claims:

Claims 1-15 are rejected and are under appeal. The Primary Examiner is requested to clarify the status of claims 13-15 in the Answer. The final rejection does not contain any detail concerning the rejections of claims 13-15.

Status of Amendments:

No claims were amended after the final Office action.

Summary of the Claimed Subject Matter:

Independent claim 1 pertains to a protective cap assembly for a sharps device. The protective cap 3 and the sharps device (e.g., a syringe with a hypodermic needle 4) is illustrated in Figs. 1-3. The claimed assembly comprises:

a receiver (5) for rigidly holding a sharps element (4) of the sharps device; page 9, lines 9-11.

a protective cap assembly (6, 7) - page 9, line 11 - attached to said receiver (5) and completely encasing the sharps element (4) in a closed position of the cap

assembly (6, 7), page 9, line 3, said cap assembly having a forward end formed with a guide (17) for said sharps element; page 12, line 6.

said receiver (5) being movably disposed in said protective cap assembly (6, 7), for movement from the closed position (illustrated in Fig. 1) - page 9, lines 2-3 - to a functional position in which the sharps element (4) projects through said needle guide (17) and from said protective cap assembly (6, 7) and the sharps device (4) is in a functional condition (illustrated in Figs. 2 and 3), page 9, lines 13-18, and from the functional position (Figs. 2, 3) to the closed position (Fig. 1) in which the sharps element is completely retracted in said protective cap assembly (6, 7), page 9, lines 2-6.

Independent claim 5 pertains to a needle cap assembly for a syringe having a distal end and a hypodermic needle projecting from the distal end (the needle cap assembly is illustrated in the figures and identified with the reference numeral 3. The syringe is identified with the numeral 1). The needle cap assembly (3) comprises:

a receiver (5, Fig. 4) rigidly mountable at the distal end (i.e., the luer lock end of the syringe) and rigidly holding the hypodermic needle (4); page 9, lines 9-11.

a protective cap (6, 7) mounted on said receiver (5) and slidable relative to said receiver (5) between a closed position (e.g., Fig. 1) - page 9, lines 2-3 - in which the protective cap encases the hypodermic needle completely and a functional position in which the hypodermic needle projects out of said protective cap (e.g., Figs. 2, 3), page 9, lines 3-4, said cap assembly having a forward end formed with a needle guide (17) for said hypodermic needle (4), page 12, line 6; and

mutually cooperating locking devices (9, 10, 11), page 9, lines 18-20, on said protective cap and on said receiver for locking said protective cap in the closed position.

Independent claim 12 pertains to a combination claim in which the needle cap assembly includes the entire assembly that allows it to be attached to the luer lock of the syringe. That is, the entire assembly includes the luer lock, the needle, the needle cap, and the attachment devices that allow the protective cap to be moved between the various positions. The claim defines the needle and needle cap assembly as follows:

a hypodermic needle (4) with a needle-side luer lock (8) configured to be attached to the syringe-side luer lock; page 9, lines 9-11,

a receiver (5) rigidly holding said hypodermic needle at said needle-side luer lock (8); page 9, lines 13-16,

a protective cap (6, 7) mounted on said receiver (5) and slidable relative to said receiver (5) between a closed position (e.g., Fig. 1) in which said protective cap encases said hypodermic needle completely, page 9, lines 2-3, and a functional position in which the hypodermic needle projects out of said protective cap (e.g., Figs. 2, 3); page 9, lines 3-5, and

mutually cooperating locking devices (9, 10, 11) on said protective cap and on said receiver for locking said protective cap in the closed position, page 10, lines 1-5.

The independent claims thus define the sharps protector in combination with the syringe and also as a retrofit combination in which the assembly may be mounted to a luer lock of a syringe.

Appellant described the device with reference to Figs. 1-3 on pages 8 and 9 of the specification. There is seen a syringe with a barrel 1 and a piston 2. The syringe is a standard device with, say, a 3 cc barrel. The syringe to be used with the invention is typically in the range from 1 to 5 cc. A distal end of the barrel 1, with reference to the plunger handle, carries a needle cap safety assembly according to the invention. While the needle 4 does not show in Fig. 1 – i.e., it is completely retracted – the needle 4 is halfway exposed in Fig. 2 and it is fully extended in Fig. 3. As will be seen from the following, the relative projection of the needle 4 from the needle safety cap is achieved by sliding the needle cap back onto the barrel 1.

Appellant outlined on page 9 of the specification, line 9, that, with reference to Fig. 4, the needle cap safety assembly 3 comprises a receiver or needle holder 5 with a standard luer lock, the needle 4, a ring clip 6, and a sleeve cap 7.

Appellant also stated on page 9 of the specification, line 13, that, with reference to Fig. 5, a luer lock 8 is integrated in the receiver 5, so that the receiver 5 with the needle 4 can be connected to a standard luer lock at the distal end of the syringe barrel 1. Two tabs 9 project from the cylindrical jacket surface of the receiver 5, at diametrically opposite points. The tabs 9 are configured to slide in tracks 10 and 11 formed in the inner wall surface of the cap 7 when the receiver is inserted. The outer diameter of the receiver 5 is adapted to the inner diameter of the cap 7 so as

to assure good slidability, yet an otherwise rigid fit to provide for a relatively stable connection. In a preferred embodiment of the invention, the outer diameter of the receiver is .540" and the inner diameter of the cap 7 is .555" in one direction and .580 in a perpendicular direction. That is, one of the two jackets (inner surface of the cap 7 or outer jacket surface of the receiver 5) may be formed slightly unround or elliptical. This aids in the functionality of the devices and provides for a better functional lock between the two components.

As set forth on page 10 of the specification, line 7, the ring clip 6 is also formed with several tabs 12. The tabs 12 project from the inner wall surface and are configured to lock into corresponding openings 13 formed in the cap 7. The tabs 12 and the openings 13 (through holes or blind bores) are formed so that the easily snap into one another during the assembly of the device, yet do not easily come apart during use. In a preferred embodiment, as illustrated in Fig. 6, the tab 12 is formed with a draft angle of approximately 30º to enable insertion and snapping into the opening 13. The backside of the tab 12, i.e., the side facing the plunger handle of the syringe, is formed with a 90º angle. This ensures proper locking of the snap ring on the cap 7.

Appellant described on page 11 of the specification, line 1 that, with reference to Fig. 7, the receiver 7 has a conical stub 13 into which a base of a needle is inserted and locked. The conicity of the inner surface of the stub 13 may be defined by a draft angle of approximately 3º, thus assuring proper hold for the needle base. The outside of the needle base is conventionally formed with a thread ridge or a tread tab so as to enable it to be threaded into the standard luer lock tread at the distal

end of the syringe. The receiver and the needle base, as well as the needle itself, may be integrally formed, with the needle directly integrated into the mold of the receiver. Alternatively, the needle may be inserted and glued into the receiver after its release from the mold.

It is further stated on page 11 of the specification, line 14 that, with reference to Fig. 8, the cap 7 is formed with the two above-mentioned sliding tracks 10 and 11, as well as a locking track 14. The locking track 14 sets the full extension of the cap 7 and thus hides the needle 4 inside the cap 7. The track 10 allows halfway extension, i.e., a "short" needle will emerge from the tip 15 of the cap 7. The track 11 allows the cap 7 to be slid back onto the barrel to its full extent, i.e., a "long" needle will emerge from the tip 15. The short needle setting may be used, for example, for drawing medication, for shallow muscle injections or for petite persons. The long needle setting would typically be used for deep muscular injection.

As set forth on page 12 of the specification, line 2, the receiver 5 is prevented from sliding backwards, out of the cap 7 beyond its locked position in the track 14 by a backwall 16 of the clip ring 6. As the receiver 5 slides forward inside the cap 7, the needle tip emerges from the tip 15. A needle guide 17 is provided for that purpose. The needle guide 17 has a conical entry segment followed by a cylindrical stabilization segment. The latter has a diameter corresponding to the largest rated needle diameter. The top of the cap is formed with a membrane 18, which may be a simple plastic foil or a spun-on plastic that ruptures as the needle emerges from the tip. The membrane 18 assures that the needle is completely encased and protected

from contamination during shipping and storage prior to use. If the device is used for multiple injections, as the needle is retracted, the membrane closes and once more protects the needle against contamination during the interim periods.

Appellant outlined in the last paragraph on page 12 of the specification, line 19 that, with reference to Fig. 8, there is illustrated an exploded X-ray view of the complete assembly, including the syringe. As shown, the needle base 19 has a thread ridge 20 the meshes with an inner thread 21 at the distal end of the syringe. The luer lock stem 22 is configured to lock into the base 19. The distal end of the syringe with the luer lock, generally identified with numeral 23, slides into the receiver 5. As shown inside the cap 7, the tracks 10 and 11 are multiplied.

As stated on page 13 of the specification, line 4, it is possible to use the new syringe and needle cap assembly without openly exposing the needle 4. For example, if medication is to be withdrawn from a container to fill the barrel, the tip 15 is placed onto the container, with the membrane 18 aligned with the membrane of the medication container. The cap 7 is then rotated so as to move the tab or tabs 9 from the locking track 14 into alignment with the sliding track 10 or 11. Since only a short needle is necessary for the withdrawal operation, the alignment with the track 10 is sufficient. The tip 15 remains in contact with the top of the container. After filling the barrel to the desired level, the cap 7 is pushed forward while the syringe and the needle are being retracted. As the needle pulls out of the container, it also retracts beyond the membrane 18 and into the cap 7. Similarly, if an injection is be administered, the tip 5 of the cap 7 is placed onto the skin, the needle is then driven out to the desired length – and at the same time driven into the patient's

tissue – all the while with the tip remaining in contact with the skin. During the withdrawal of the needle, once more, the tip 15 remains in contact with the skin, until the needle is hidden inside the cap 7.

It is mentioned on page 14 of the specification, line 1 that the various rotational positions may be adapted to the specific use of the device. For instance, in the preferred embodiment, the locking position and the sliding positions (tracks 10, 11) are set so that, when the cap protector assembly is unscrewed from the syringe, the assembly is automatically set to the locking position with the needle completely retracted inside the inner space. This provides for a sharps protector with added safety.

Appellant also stated on page 14 of the specification, line 10 that the inside of the cap 7 is formed with a draft angle such that, when the receiver 5 is fully pushed forward (the needle 4 is completely extended), the receiver 5 is friction locked in the cap 7. This makes for a very stable assembly during its use.

As depicted in the last paragraph on page 14 of the specification, line 16, the advantages of the novel device are immediately apparent. By way of example, the device provides for safe medication withdrawal with a clearly reduced likelihood of a needle-stick injury. Safe and sterile medication storage is assured until the timing of the actual injection and between partial injections, because the safety cap completely encloses the sharps element. The full enclosure also assures safe transportation to the patient or laboratory. The injection can be effected without ever exposing the needle to the patient. The device can replicate two or more

needle sizes for a variety of injection depths. Finally, the device can be locked and thus protected against accidental sharps injury following the injection.

Appellant mentioned on page 15 of the specification, line 5 that the novel device is suitable for a variety of applications. For instance, all intramuscular injections can be performed, as well as all I.V. injections, and lidocaine injections. Finally, as noted above, the device is well suited for medication withdrawal.

Grounds of Rejection to be Reviewed on Appeal

1. Whether or not claim 12 is anticipated by Lee et al. (US 5,201,721, hereinafter "Lee") under 35 U.S.C. § 102(b).

2. Whether or not claims 1, 4, 5, 9, and 10 are obvious over Lee (?) in view of Stehrenberger et al. (US 5,269,761, hereinafter "Stehrenberger") under 35 U.S.C. § 103.

3. Whether or not claims 2, 3, 7, and 8 are obvious over Lee in view of Stehrenberger and further in view of Grabis et al. (US 6,322,540, hereinafter "Grabis") under 35 U.S.C. § 103.

4. Whether or not claim 6 is obvious over Lee in view of Stehrenberger and further in view of Olovson (US 2002/0193749) under 35 U.S.C. § 103.

5. Whether or not claim 11 is obvious over Lee in view of Stehrenberger in view of Grabis and further in view of Gregorio (US 5,346,475) under 35 U.S.C. § 103.

Arguments:

1. Claim 12 is not anticipated by Lee:

Claim 12 requires, *inter alia*, that the protective cap "encases said hypodermic needle completely." Lee's tubular sheath surrounds the hypodermic needles on the sides. The sheath is completely open in the front. It does, therefore, not encase the needle. It certainly does not encase the needle "completely."

When applicant presented this argument, the Examiner responded that she "defines encase to mean enclose or surround as with a fence or wall. The cap of Lee fits this definition." Final rejection, page 5, top. This definition is patently wrong. In order to clearly and unambiguously define the terminology of "completely encasing," applicant provided a careful explanation that defines the term in the specification. To wit:

> The membrane 18 assures that the needle is completely encased and protected from contamination during shipping and storage prior to use. If the device is used for multiple injections, as the needle is retracted, the membrane closes and once more protects the needle against contamination during the interim periods.

Specification, page 12. The term as defined provides for mechanical protection and for protection against contamination. Neither objective is satisfied by the combination as shown by Lee.

Lee's needle sheath is open in the front. It does not encase the needle completely. At least for this reason, Lee does not anticipate the invention defined in claim 12.

Claim 12 is patentable over the art of record. None of the prior art references show or suggest a protective cap assembly that does not comprise the syringe itself. Here, we have a protective cap and needle assembly, which is connected *in toto* to

the luer lock of the syringe. It is a self-contained assembly that can be retrofitted to an existing syringe without structurally changing the syringe or attaching anything to the syringe barrel or the head.

In other words, applicant's device is a separately attached luer-locked device. The syringe or the syringe barrel is not compromised. In an advantageous modification, the novel assembly defines two or more functional needle positions, for instance, for shallow injections and for deep injections.

2. Claims 1, 4, 5, 9, and 10 are not obvious over Lee and Stehrenberger:

The secondary reference was cited with regard to the claimed "needle guide." It is respectfully submitted that Stehrenberger does not disclose a needle guide. Instead, the secondary reference teaches that

> [t]he sheath has a hollow interior which tapers at its distal end 24 to a narrow opening 26 which permits the needle 16 to pass when the sheath is retracted.

Stehrenberger, col. 3, lines 6-8. That is, the reference does not show a "needle guide" in the sense of the claimed invention. The reference only shows a narrowing of the forward end of the sheath.

If the primary reference Lee were modified with this feature, the completely open sheath tube of Lee would be narrowed. Nothing in the Stehrenberger teaching, however, would prompt the person of skill in the art to provide a "needle guide." The narrowed opening of the secondary reference still has a diameter that is a multiple of the needle diameter. In fact, the diameter of the opening is apparently chosen to steady the needle base when the cap is fully retracted.

The needle guide of the claimed invention, on the other hand, is provided to "guide" and "steady" the needle. As explained on page 12 of appellant's specification, the needle guide is formed with a "conical entry segment" and with a "cylindrical stabilization segment" with a diameter that corresponds to the needle diameter. We are, of course, mindful of the fact that these features do not appear in the claim. The term "needle guide," nevertheless, carries a connotation which cannot be read on the slight narrowing provided by Stehrenberger.

Even if, arguendo, the foregoing "needle guide argument" were considered deficient, claims 1 and 5 would still not be obvious over the combined teachings of Lee and Stehrenberger. The combination would still lack the "completely encasing" limitation because the secondary reference only narrows at the tip but does not completely encase the hypodermic needle.

Claims 1 and 5 are not obvious over Lee and Stehrenberger. Claims 4, 9, and 10 depend from claims 1 and 5, respectively, and they are therefore not obvious either.

3. Claims 2, 3, 7, and 8 are not obvious over Lee in view of Stehrenberger and further in view of Grabis:

The combination does not render the claimed invention obvious. Grabis is concerned with the head attachment, i.e., the mounting of the protective cap to the barrel. The secondary reference also has a completely open cylinder forming the protective cap.

In fact, the disclosure of Grabis et al. is quite useful in showing how the invention differs from the prior art. There, a completely separate assembly with a ring 3 and a cylinder 10 is attached to the barrel of the syringe. The needle and the luer lock are not impacted and they remain completely separate from the protective cap.

Appellant – as illustrated in Fig. 9, for example – provides for a different solution. Here, the protective cap and the needle form a unit and that unit is attached to the syringe via the luer lock (This is specifically recited in claim 12.)

4. Claim 6 is not obvious over Lee in view of Stehrenberger and further in view of Olovson:

The further secondary reference to Olovson indeed teaches a protective membrane. Olovson has a protective cylinder 2 similar to the cylinder 28 of Lee. The secondary reference further teaches that a membrane 2b may be provided at the end-part 2a. The membrane 2b is to seal off the inner diameter of the tube. See, p. 4, [0073]. Olovson further explains that his protective cap "consists essentially of a section of tubing with a circular cross-section and constant radius . . . " and that the membrane is very thin ("membrane thickness much less than the thickness of the tube 2' material," p. 4, [0074]).

If one were to use the pertinent teaching of Olovson and provide a thin membrane to the sheath 28 of Lee, one could probably consider the resulting protective cap to form a "completely encasing cap," at least until the membrane is pierced. According

to Stehrenberger, the forward end would be narrowed to a certain extent, but still only to an opening that is a multiple of the needle diameter.

Claim 6 calls for a needle guide (or a sharps guide) at the forward end of the protective cap. The needle guide ensures that the opening at the tip is as small as possible and that the exposure towards the luer lock is minimized. This aids in maintaining proper sterility of the assembly and, further, the guide aids in bracing the needle during use at the very forward end and thus adding a further element of stability to the assembly.

In fact, the needle guide and its bracing of the needle allow for the multiple functional positions of the needle (i.e., the needle is securely braced in the forward end even in its half-retracted position shown in Fig. 2). Neither structure nor functionality is met by the thin membrane of the reference teachings. The very thin membrane of Olovson is provided to maintain sterility of the system prior to its use. While the reference does not provide any details, it is safe to assume that once the membrane is pierced it is probably destroyed (e.g., ripped). More importantly, the thin membrane cannot function as a guide for the needle and it certainly does not brace the needle.

The combined teachings of Lee, Stehrenberger, and Olovson, therefore, do not render obvious the invention of claim 6.

5. Claim 11 is not obvious over Lee in view of Stehrenberger in view of Grabis and further in view of Gregorio:

The further secondary reference to Gregorio provides for a one-time use needle assembly. There, the needle is exposed in the functional position. After the syringe has been used, the shield is pushed forward and locked in place. That is, the used needle is protected.

Gregorio indeed provides only for a single functional position. The fully extended position is shown in Fig. 1. This is the only functional position contemplated by Gregorio. After use, the needle is retracted into the shield, with the ratchet teeth 44 incrementally preventing forward movement.

Claim 11 is patentable over the art of record.

The honorable Board is therefore respectfully urged to reverse the final rejection of the Primary Examiner.

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Claims Appendix:

1. A protective cap assembly for a sharps device, comprising:

a receiver for rigidly holding a sharps element of the sharps device;

a protective cap assembly attached to said receiver and completely encasing the sharps element in a closed position of the cap assembly, said cap assembly having a forward end formed with a guide for said sharps element;

said receiver being movably disposed in said protective cap assembly, for movement from the closed position to a functional position in which the sharps element projects through said needle guide and from said protective cap assembly and the sharps device is in a functional condition, and from the functional position to the closed position in which the sharps element is completely retracted in said protective cap assembly.

2. The assembly according to claim 1, wherein said protective cap assembly includes a clip ring and a protective cap attached to said clip ring, and wherein said clip ring is configured to limit a movement of said receiver in one direction and said cap is configured to limit the movement of said receiver in another direction.

3. The assembly according to claim 2, wherein said receiver has a tab formed on a substantially cylindrical jacket surface thereof, and said protective cap assembly is formed with at least one groove in an inner jacket surface thereof, defining a track within which said tab slides from the locked position to the functional position.

4. The assembly according to claim 1, wherein the sharps device is a syringe and the sharps element is a hypodermic needle.

5. A needle cap assembly for a syringe having a distal end and a hypodermic needle projecting from the distal end, the needle cap assembly comprising:

a receiver rigidly mountable at the distal end and rigidly holding the hypodermic needle;

a protective cap mounted on said receiver and slidable relative to said receiver between a closed position in which the protective cap encases the hypodermic needle completely and a functional position in which the hypodermic needle projects out of said protective cap, said cap assembly having a forward end formed with a needle guide for said hypodermic needle; and

mutually cooperating locking devices on said protective cap and on said receiver for locking said protective cap in the closed position.

6. The needle cap assembly according to claim 5, wherein said protective cap has a tip formed with an opening through which the needle projects in the functional position, and a membrane covering and substantially sealing said opening when the protective cap is in the closed position and the needle is completely retracted inside said cap.

7. The needle cap assembly according to claim 5, which comprises a clip ring connected with said protective cap, and wherein said clip ring is configured to limit

a movement of said receiver in one direction and said protective cap is configured to limit the movement of said receiver in another direction.

8. The needle cap assembly according to claim 7, wherein said receiver has a tab formed on a substantially cylindrical jacket surface thereof, and said protective cap is formed with at least one groove in an inner jacket surface thereof, defining a track within which said tab slides from the locked position to the functional position.

9. A syringe assembly, comprising a syringe having a plunger and a barrel with a distal end, the needle cap assembly according to claim 5, a needle held in said receiver and mounted, together with said receiver and said needle cap assembly, to said distal end of said barrel.

10. The syringe assembly according to claim 9, wherein said distal end of said barrel is formed with a luer lock and said needle cap assembly and said needle together are formed to be mounted on said luer lock.

11. The protective cap assembly according to claim 3, wherein said receiver and said protective cap assembly are configured to define at least two functional positions in which said sharps element projects from said protective cap assembly by at least two different amounts.

12. In combination with a syringe device having a syringe-side luer lock, a needle and needle cap assembly, the assembly comprising:

a hypodermic needle with a needle-side luer lock configured to be attached to the syringe-side luer lock;

a receiver rigidly holding said hypodermic needle at said needle-side luer lock;

a protective cap mounted on said receiver and slidable relative to said receiver between a closed position in which said protective cap encases said hypodermic needle completely and a functional position in which the hypodermic needle projects out of said protective cap; and

mutually cooperating locking devices on said protective cap and on said receiver for locking said protective cap in the closed position.

13. The protective cap assembly according to claim 12, wherein said locking devices are configured to define at least two functional positions in which said hypodermic needle projects from said protective cap assembly by at least two different amounts.

14. The needle cap assembly according to claim 12, wherein said protective cap has a tip formed with an opening through which said needle projects in the functional position, and a membrane covering and substantially sealing said opening when the protective cap is in the closed position and the needle is completely retracted inside said cap.

15. The needle cap assembly according to claim 12, which comprises a clip ring connected with said protective cap, and wherein said clip ring is configured to limit

a movement of said receiver in one direction and said protective cap is configured to limit the movement of said receiver in another direction.

Evidence Appendix:

No evidence pursuant to §§ 1.130, 1.131, or 1.132 or any other evidence has been entered by the Examiner and relied upon by appellant in the appeal.

Related Proceedings Appendix:

No prior or pending appeals, interferences or judicial proceedings are in existence which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in this appeal. Accordingly, no copies of decisions rendered by a court or the Board are available.